

110TH CONGRESS  
2D SESSION

# H. R. 7199

To establish programs that use the Internet to provide to patients and health care practitioners coordinated information on diseases and other conditions, and for other purposes.

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## IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 28, 2008

Mr. CANNON introduced the following bill; which was referred to the  
Committee on Energy and Commerce

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## A BILL

To establish programs that use the Internet to provide to patients and health care practitioners coordinated information on diseases and other conditions, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*  
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Medical Information  
5 and Treatment Access Act”.

6 **SEC. 2. TABLE OF CONTENTS.**

7 The table of contents for this Act is as follows:

Sec. 1. Short title.

Sec. 2. Table of contents.

Sec. 3. Findings.

TITLE I—FEDERAL INTERNET SITE FOR CONSOLIDATION AND  
TRANSLATION OF INFORMATION ON DISEASES AND OTHER  
CONDITIONS

Sec. 101. Internet site.

TITLE II—ADDITIONAL FORUMS FOR EXCHANGE OF HEALTH  
INFORMATION

Sec. 201. Forum regarding off-label uses of new drugs and devices.

Sec. 202. John Eisenberg forum regarding surgical procedures.

Sec. 203. John Eisenberg forum regarding complementary and alternative medicine; dietary supplements and food.

TITLE III—GENERAL PROVISIONS

Sec. 301. Definitions.

Sec. 302. Effective dates.

1 **SEC. 3. FINDINGS.**

2 The Congress finds as follows:

3 (1) The Congress and the American people de-  
4 sire to live healthy lives and foster an effective and  
5 efficient health care system. This system requires  
6 timely, accurate, and ever-improving information re-  
7 sources. This will foster maximization of health care  
8 outcomes and help health care practitioners and pa-  
9 tients partner for more effective results.

10 (2) The Internet is a unique tool offering access  
11 to great volumes of information. Some is accurate  
12 and some is not. There has also been extensive gov-  
13 ernment investment in placing medical information  
14 on the Internet in many diverse places.

15 (3) There is a need to consolidate and translate  
16 this myriad of information for physicians and con-  
17 sumers, from the listing of clinical trials to the pro-

1        protocols for treatment of various diseases and condi-  
2        tions, as well as the integration of new discoveries  
3        and the evaluations of outcomes-based examinations  
4        of drugs and devices for conditions other than those  
5        for which they are already approved. This will lead  
6        to more accurate treatment, fewer medical errors,  
7        and more successful outcomes, while also protecting  
8        patients, a physician's right to practice medicine,  
9        and a patient's right to access the health care the  
10       patient desires.

11            (4) The Food and Drug Administration is  
12        uniquely qualified to assist the Nation in fulfilling  
13        this mission to improve health care for the benefit  
14        of Americans. The Administration already coordi-  
15        nates the information needs of many government  
16        agencies and equivalent regulatory bodies in other  
17        countries.

18            (5) In providing Internet-based forums for ob-  
19        taining and disseminating health-related information  
20        (including information on surgical procedures; com-  
21        plimentary and alternative medicine; dietary supple-  
22        ments and food; and unapproved treatments), the  
23        Food and Drug Administration should work closely  
24        with educational institutions, schools of medicine,  
25        and other appropriate private entities and ensure

1       that the expertise of such entities is appropriately  
2       utilized.

3       **TITLE I—FEDERAL INTERNET**  
4       **SITE FOR CONSOLIDATION**  
5       **AND TRANSLATION OF INFOR-**  
6       **MATION ON DISEASES AND**  
7       **OTHER CONDITIONS**

8       **SEC. 101. INTERNET SITE.**

9       (a) IN GENERAL.—The Secretary of Health and  
10      Human Services, acting through the Commissioner of  
11      Food and Drugs, shall carry out a program whose mission  
12      is, through an Internet site maintained for purposes of  
13      the program—

14               (1) to consolidate and translate health care in-  
15      formation that is available to the public from Fed-  
16      eral agencies, linking the various health-related  
17      Internet sites of such agencies; and

18               (2) to assist in the translation and reporting of  
19      disease or condition protocols for physicians and lay  
20      persons.

21      (b) INFORMATION ON DISEASES AND OTHER CONDI-  
22      TIONS.—The Secretary shall ensure that the Internet site  
23      under subsection (a) has capacities that enable a user of  
24      the site to enter the name of a disease or other health  
25      condition and obtain Internet links appropriate to health

1 care providers, and links appropriate to lay persons, that  
2 provide—

3 (1) an explanation of the health condition; and

4 (2) information on all available treatment pro-  
5 tocols, including—

6 (A) standard medical practice protocols;

7 and

8 (B) any clinical trials, and any outcomes-  
9 based treatment protocols, that—

10 (i) are being conducted or supported  
11 by the National Institutes of Health;

12 (ii) are included in the registry and  
13 results data bank under section 402(j) of  
14 the Public Health Service Act (42 U.S.C.  
15 282(j));

16 (iii) are being conducted pursuant to  
17 the Federal Food, Drug, and Cosmetic Act  
18 or section 351 of the Public Health Service  
19 Act;

20 (iv) are being conducted pursuant to  
21 section 201 of this Act; or

22 (v) are identified pursuant to section  
23 201 or 202 of this Act or pursuant to sec-  
24 tion 485D(i) of the Public Health Service  
25 Act (as added by section 203 of this Act).

1 (c) FEDERAL DATABASES.—Internet links under  
2 subsection (b) shall include the following:

3 (1) Links that provide information on how to  
4 enroll in a clinical trial referred to in subsection  
5 (b)(2)(B) and how to be treated under an outcomes-  
6 based treatment protocol referred to in such sub-  
7 section.

8 (2) Links to Federal electronic databases that  
9 are available to the public and provide disease-spe-  
10 cific or condition-specific information, including such  
11 databases of the National Institutes of Health, the  
12 Centers for Disease Control and Prevention, and the  
13 Food and Drug Administration.

14 (3) A link to the Internet site under section  
15 204(a) (relating to research and treatments carried  
16 out pursuant to section 201, and the identity of the  
17 health care practitioners involved).

18 (4) A link to the Internet sites under sections  
19 201 and 202 of this Act and the Internet site under  
20 section 485D(i) of the Public Health Service Act (as  
21 added by section 203 of this Act).

22 (d) DATE CERTAIN FOR OPERATION OF PROGRAM.—  
23 The Internet site under subsection (a) shall be established  
24 and ready for use by health care practitioners and lay per-

1 sons not later than two years after the date of the enact-  
2 ment of this Act.

3 **TITLE II—ADDITIONAL FORUMS**  
4 **FOR EXCHANGE OF HEALTH**  
5 **INFORMATION**

6 **SEC. 201. FORUM REGARDING OFF-LABEL USES OF NEW**  
7 **DRUGS AND DEVICES.**

8 (a) IN GENERAL.—The Secretary, acting through the  
9 Commissioner of Food and Drugs, shall (directly or  
10 through contract) establish a program under which the  
11 following occur:

12 (1) Health care practitioners submit to the Sec-  
13 retary information obtained in the course of their  
14 professional practices regarding off-label uses of new  
15 drugs and devices.

16 (2) The Secretary maintains the information re-  
17 ceived under paragraph (1); makes such information  
18 available to health care practitioners and the general  
19 public through one or more Internet sites; and re-  
20 ceives, maintains, and makes available through such  
21 site appropriate comments and information provided  
22 in response to such information.

23 (3) The Secretary carries out paragraph (2) in  
24 a manner reasonably calculated to provide a forum

1 for obtaining and disseminating information, includ-  
2 ing clinical data, toward the following goals:

3 (A) Identifying off-label uses of new drugs  
4 and devices that are reasonable candidates for  
5 approval under section 505 or 515 of the Fed-  
6 eral Food, Drug, and Cosmetic Act or under  
7 section 351 of the Public Health Service Act.

8 (B) Identifying off-label uses of new drugs  
9 and devices that constitute a threat to the pub-  
10 lic health.

11 (C) Making available to the Secretary in-  
12 formation for uses with respect to promoting in-  
13 novations in evidence-based clinical practice and  
14 health care technologies under title IX of the  
15 Public Health Service Act.

16 (b) VOLUNTARY PARTICIPATION.—Subsection (a)  
17 may not be construed as requiring that any health care  
18 practitioner or other person participate in the program  
19 under such subsection.

20 (c) CERTAIN AUTHORITIES.—The posting by the Sec-  
21 retary of information on an Internet site under subsection  
22 (a) is subject to the following:

23 (1) The Secretary may not post information  
24 submitted by a health care practitioner unless the  
25 practitioner authorizes the Secretary to include in



1 the posting the identity and the business address of  
2 the practitioner.

3 (2) The Secretary may impose reasonable re-  
4 strictions on the format and volume of information  
5 to be posted and on the frequency of postings.

6 (d) CRITERIA.—Not later than one year after the  
7 date of the enactment of this Act, the Secretary shall by  
8 regulation issue criteria for carrying out this section.

9 **SEC. 202. JOHN EISENBERG FORUM REGARDING SURGICAL**  
10 **PROCEDURES.**

11 (a) IN GENERAL.—The Secretary, acting through the  
12 Commissioner of Food and Drugs, shall (directly or  
13 through contract) establish a program under which the  
14 following occur:

15 (1) Health care practitioners submit to the Sec-  
16 retary information obtained in the course of their  
17 professional practices regarding surgical procedures.

18 (2) The Secretary maintains the information re-  
19 ceived under paragraph (1); makes such information  
20 available to health care practitioners and the general  
21 public through one or more Internet sites; and re-  
22 ceives, maintains, and makes available through such  
23 site appropriate comments and information provided  
24 in response to such information.

1           (3) The Secretary carries out paragraph (2) in  
2           a manner reasonably calculated to provide a forum  
3           for obtaining and disseminating information, includ-  
4           ing clinical data, toward the following goals:

5                   (A) Identifying innovative surgical proce-  
6                   dures.

7                   (B) Identifying surgical procedures that  
8                   constitute a threat to the public health.

9                   (C) Making available to the Secretary in-  
10                  formation for uses with respect to promoting in-  
11                  novations in evidence-based clinical practice and  
12                  health care technologies under title IX of the  
13                  Public Health Service Act.

14          (b) VOLUNTARY PARTICIPATION.—Subsection (a)  
15          may not be construed as requiring that any health care  
16          practitioner or other person participate in the program  
17          under such subsection.

18          (c) CERTAIN AUTHORITIES.—The posting by the Sec-  
19          retary of information on an Internet site under subsection  
20          (a) is subject to the following:

21                  (1) The Secretary may not post information  
22                  submitted by a health care practitioner unless the  
23                  practitioner authorizes the Secretary to include in  
24                  the posting the identity and the business address of  
25                  the practitioner.

1           (2) The Secretary may impose reasonable re-  
 2           strictions on the format and volume of information  
 3           to be posted and on the frequency of postings.

4           (d) CRITERIA.—Not later than one year after the  
 5           date of the enactment of this Act, the Secretary shall by  
 6           regulation issue criteria for carrying out this section.

7   **SEC. 203. JOHN EISENBERG FORUM REGARDING COM-**  
 8                           **PLEMENTARY AND ALTERNATIVE MEDICINE;**  
 9                           **DIETARY SUPPLEMENTS AND FOOD.**

10          Section 485D of the Public Health Service Act is  
 11          amended—

12                 (1) by redesignating subsections (i) and (j) as  
 13                 subsections (j) and (k), respectively; and

14                 (2) by adding after subsection (h) the following  
 15                 subsection:

16                 “(i) JOHN EISENBERG FORUM FOR EXCHANGE OF  
 17                 INFORMATION.—

18                         “(1) IN GENERAL.—The Director of the Center,  
 19                         in consultation with the Commissioner of Food and  
 20                         Drugs, shall (directly or through contract) establish  
 21                         a program under which the following occur:

22                                 “(A) Health care practitioners submit to  
 23                                 the Director information obtained in the course  
 24                                 of their professional practices regarding com-  
 25                                 plementary and alternative treatment, diag-

1 nostic and prevention modalities, disciplines and  
2 systems.

3 “(B) The Director maintains the informa-  
4 tion received under subparagraph (A); makes  
5 such information available to health care practi-  
6 tioners and the general public through estab-  
7 lishing one or more Internet sites; and receives,  
8 maintains, and makes available through such  
9 site appropriate comments and information pro-  
10 vided in response to such information.

11 “(C) The Director carries out subpara-  
12 graph (B) in a manner reasonably calculated to  
13 provide a forum for obtaining and dissemi-  
14 nating information, including clinical data, to-  
15 ward the following goals:

16 “(i) Identifying alternative treatment,  
17 diagnostic and prevention systems, modal-  
18 ities, and disciplines that should be inte-  
19 grated with the practice of conventional  
20 medicine as a complement to such medi-  
21 cine and integrated into health care deliv-  
22 ery systems in the United States.

23 “(ii) Identifying any alternative med-  
24 ical practices or procedures that constitute  
25 a threat to the public health.

1                   “(iii) Making available to the Commis-  
2                   sioner of Food and Drugs information for  
3                   uses with respect to promoting innovations  
4                   in evidence-based clinical practice and  
5                   health care technologies under title IX of  
6                   the Public Health Service Act.

7                   “(2) DIETARY SUPPLEMENTS AND FOOD.—In  
8                   consultation with the Commissioner of Food and  
9                   Drugs, the Director of the Center shall carry out the  
10                  following:

11                  “(A) Activities under paragraph (1) shall  
12                  include carrying out such paragraph with re-  
13                  spect to information that relates to the effects  
14                  of dietary supplements and food on diseases  
15                  and disorders and is obtained by the practi-  
16                  tioners in the course of their professional prac-  
17                  tices and submitted to the Director.

18                  “(B) With respect to paragraph (1)(C) as  
19                  applied for purposes of this paragraph, the  
20                  goals shall be the following:

21                  “(i) Identifying dietary supplements  
22                  and food and uses of such supplements  
23                  and food that are of clinical benefit in  
24                  treating particular diseases or disorders.

1 “(ii) As appropriate, providing for the  
2 publication of authoritative statements,  
3 within the meaning of section  
4 403(r)(3)(C)(i) of the Federal Food, Drug,  
5 and Cosmetic Act, about the relationship  
6 between a nutrient and a disease or health-  
7 related condition.

8 “(iii) Carrying out paragraph  
9 (1)(C)(iii) with respect to dietary supple-  
10 ments.

11 “(3) VOLUNTARY PARTICIPATION.—Paragraph  
12 (1) may not be construed as requiring that any  
13 health care practitioner or other person participate  
14 in the program under such paragraph.

15 “(4) CERTAIN AUTHORITIES.—The posting by  
16 the Director of the Center of information on the  
17 Internet site under paragraph (1) is subject to the  
18 following:

19 “(A) The Director may not post informa-  
20 tion submitted by a health care practitioner un-  
21 less the practitioner authorizes the Director to  
22 include in the posting the identity and the busi-  
23 ness address of the practitioner.

24 “(B) The Director may impose reasonable  
25 restrictions on the format and volume of infor-

1           mation to be posted and on the frequency of  
2           postings.

3           “(5) CRITERIA.—Not later than one year after  
4           the date of the enactment of the Medical Informa-  
5           tion and Treatment Access Act, the Secretary shall  
6           by regulation issue criteria for carrying out this sub-  
7           section.

8           “(6) DEFINITIONS.—For purposes of this sub-  
9           section, the terms ‘dietary supplement’ and ‘food’  
10          have the meaning given such terms in section 201  
11          of the Federal Food, Drug, and Cosmetic Act.”.

## 12                   **TITLE III—GENERAL** 13                   **PROVISIONS**

### 14   **SEC. 301. DEFINITIONS.**

15          For purposes of this Act:

16               (1) The terms “device”, “labeling”, and “new  
17               drug” have the meanings given such terms in section  
18               201 of the Federal Food, Drug, and Cosmetic Act  
19               (21 U.S.C. 301).

20               (2) The term “off-label use”, with respect to a  
21               new drug or a device, means a use not included in  
22               the labeling approved for the drug or device pursu-  
23               ant to section 505, 510, or 515 of the Federal Food,  
24               Drug, and Cosmetic Act (21 U.S.C. 355, 360c,

1       360e) or section 351 of the Public Health Service  
2       Act (42 U.S.C. 262).

3               (3) The term “Secretary” means the Secretary  
4       of Health and Human Services.

5   **SEC. 302. EFFECTIVE DATES.**

6       (a) IN GENERAL.—Subject to subsection (b)—

7               (1) sections 201 and 202 take effect on the  
8       date on which a final rule takes effect pursuant to  
9       sections 201(d) and 202(d), respectively; and

10              (2) the amendment made by section 203 takes  
11       effect on the date on which the final rule required  
12       under section 485D(i)(5) of the Public Health Serv-  
13       ice Act (as added by such amendment) takes effect.

14       (b) ISSUANCE OF CRITERIA.—Sections 201(d) and  
15       202(d) of this Act and section 485D(i)(5) of the Public  
16       Health Service Act (as added by section 203 of this Act)  
17       take effect on the date of the enactment of this Act.

○